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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/966,447 | 09/28/2001 | David Christian Lentz | CRD-0957 | 2148 |

27777 7590 10/30/2007
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| EXAMINER |
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RYCKMAN, MELISSA K

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| ART UNIT | PAPER NUMBER |
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3773

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10/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 09/966,447 | Applicant(s) LENTZ ET AL. | |
| | Examiner Melissa Ryckman | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on received on 8/15/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to claims 8/15/07.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster et al. (US 5234447) in view of Swanson et al. (US 6113612). Kaster teaches a device for joining substantially tubular organs in a living organism comprising: an anastomosis device (12) for connecting a graft vessel to a target vessel such that the two vessels are in fluid communication, the anastomosis device including a fastening flange (46) and a plurality of staples (43) connected the fastening flange and having sharpened ends with barbs (fig. 8), the fastening flange comprising a single wire ring (46, this band is considered

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a wire) structure having a rippled wave-like configuration (the portion of 46 near 44 inherently bends a small amount when 44 is attached to the blood vessel, this causes a wave on a small scale) for a reduced profile for delivery (it is noted that since the ends of flange 46 are not fused, see fig. 10, the device is configured to have a reduced profile for delivery) and the plurality of staples being configured to spring from a restrained position (fig. 14) to a position substantially perpendicular to the ring structure, and finally to an inverted loop position through the graft vessel and target vessel (fig. 19);

Kaster fails to teach a biocompatible vehicle affixed to at least a portion of the anastomosis device; and at least one agent in therapeutic dosages incorporated into the biocompatible vehicle. Swanson teaches an anastomosis device wherein the device includes a biocompatible vehicle (522, 530) being made from polymer materials for carrying drugs to facilitate healing and or sealing (Column 13, proximate lines 3-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kaster with a biocompatible vehicle including a therapeutic agent as taught by Swanson in order to carry drugs to facilitate healing and or sealing of the anastomosis site.

Claims 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kaster and Swanson et al. Although the combination of Kaster and Swanson et al. does not disclose the anastomosis device comprising the polymeric matrix and drugs as claimed, the polymeric matrix and drugs as

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claimed are well known in the art that are provided on a stent or an anastomosis device in order to deliver drug for treating and healing or preventing restenosis at an implantation site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the polymeric matrix and drugs as claimed in order to effectively deliver the drug for treating, healing and preventing restenosis at an implantation site.

Regarding to the specific weight percentage of polymers of a copolymer as claimed, it is well known in the art to make a copolymer out of various percentages by weight in order to provide a polymer matrix with a desire property/characteristic. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to varying the property/characteristic of the polymeric matrix by varying the percentages by weight of each residue in order to maximize the property/characteristic of polymeric matrix for use in certain drug application.

Response to Arguments

Applicant's arguments filed 8/15/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- The amendments including the wire ring structure having a rippled wave-like configuration overcomes Kaster and Swanson

The examiner respectfully disagrees with the applicant, as stated in the above rejection Kaster teaches the wire ring structure having a rippled wave-like configuration.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

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PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

A handwritten signature in black ink, appearing to read "M. Hayes", is positioned above the printed name.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER